



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/440,384 | 11/15/1999 | HOWARD A. KINGSFORD | 05918-153001 | 2883 |

7590 11/28/2001

FISH & RICHARDSON P C
225 FRANKLIN STREET
BOSTON, MA 021102804

EXAMINER

PATTERSON, MARC A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1772

8

DATE MAILED: 11/28/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/440,384

Applicant(s)

KINGSFORD, HOWARD A.

Examiner

Marc A Patterson

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1772

DETAILED ACTION

REPEATED REJECTIONS

1. The 35 U.S.C. 112, second paragraph rejection of Claim 1, 10 and 17, of record on page 2 of the previous Action, are repeated.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. term 'distal' has not been defined and therefore renders the claim indefinite. For purposes of examination, 'distal tip' will be assumed to mean 'tip.' Correction and / or clarification is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1772

5. Claims 1 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No. 5,031,609) and Coates (U.S. Patent No. 4,219,019).

With regard to Claim 1, Reed et al. disclose an array (plurality) of surfaces having a pointed shape (therefore a tip; column 3, lines 16 – 22; column 60 – 66) formed of plastic (column 3, lines 40 – 42) which is used to pierce (penetrate) skin (column 4, lines 28 – 32); it is therefore a skin attachment member of plastic resin, and is configured to penetrate into the epidermal skin layer; the skin attachment has a sheet form backing from which the penetrating elements extend integrally (base; column 7, lines 26 – 27), and is used as a bandage (column 5, lines 21 – 26); the skin penetrating elements include a retention barb extending from an outer surface of the skin penetrating element. Reed et al. fail to disclose a skin penetrating element which is sized to limit painful contact with the nerves below the epidermal skin layer, and barbs which are configured to cooperate to resist removal of the skin attachment member from skin. The size and configuration of the penetrating elements, however, would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. *In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980)*.

With respect to Claim 4, the surfaces of the skin penetrating elements have pointed shapes (column 3, lines 16 – 22; column 60 – 66), and therefore, pointed tips.

With respect to Claim 10, each skin penetrating element includes two barbs (column 3, lines 60 – 66, Figure 6).

With respect to Claim 13, Reed et al. fail to disclose a skin attachment member comprising nylon. Fye teaches the use of nylon in the making of bandages, for the purpose of

Art Unit: 1772

making bandages which are light – weight and hand – washable (column 2, lines 34 – 39). It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for nylon in Reed et al. in order to make bandages which are hand – washable as taught by Fye.

With respect to Claim 14 and 15, Reed et al. fail to disclose a skin attachment member comprising polyethylene terephthalate (which is a polyester). Coates teaches the use of polyethylene terephthalate in the making of bandages, for the purpose of making bandages which possesses bulk and conformability. It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for polyethylene terephthalate in Reed et al. in order to make bandages which possesses bulk and conformability as taught by Coates.

With regard to Claim 16, the scope of the claim falls within the limitation of Reed et al. as discussed above. The process of making the skin attachment member (product – by – process) is given little patentable weight. Applicant would need to demonstrate, by verified showing, the unexpected advantages accruing from making the elements by molding, rather than etching, as claimed.

With regard to Claim 17, the skin penetrating elements have pointed shapes, and therefore define depressions on the surface.

With regard to Claims 2, 3, 5 – 9, 11 – 12 and 18, Reed et al. and Fye and Coates fail to disclose a skin penetrating element comprising a cone – shaped body, and a cone – shaped body having a diameter of about 0.003”, and a skin penetrating element having a diameter of 0.003”, and a skin penetrating element having a length of 0.012” and a backing having a thickness of

Art Unit: 1772

0.003 to 0.008", and a retention barb which is 0.008" to 0.0095" from the backing, and a retention barb with a length of 0.0001", and a retention barb which tapers from a thickness of 0.0001" to a point at an angle of 72 degrees, and a skin attachment member having a density of 400 skin penetrating elements in a 0.1 in² area and the elements are spaced apart from each other a distance of 0.003, and the elements are perpendicular to the backing. However, the shape of the skin penetrating elements (including diameter), the length of the elements, the thickness of the backing, the location of the retention barb, the length of the retention barb, the angle and thickness from which the retention barb tapers, the density and spacing of skin penetrating elements, and the angle of the elements relative to the backing would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

As to newly submitted Claim 19, Reed et al teach that it is equivalent to use the same material or different materials for all of the layers (the base, support and head are made from plastic, or the base and support are made from Si and the head from SiO₂; column 3, lines 35 – 46); the claimed aspect of the backing and skin penetrating elements, including each barb, being made from the same plastic resin therefore reads on Reed et al. With regard to the claimed aspect of the element being molded, the scope of the claims falls within the limitations of Reed et al. The method making the skin – penetrating element (product – by – process) is given little patentable weight. Applicant would need to demonstrate, by verified showing, the unexpected advantages accruing from making the elements by molding, rather than etching, as claimed.

As to newly submitted Claim 20, as stated previously, the penetrating element has a pointed shape; it therefore tapers continuously from the base to the tip.

Art Unit: 1772

As to newly submitted Claim 23, as stated previously, the barb extends from the outer surface of the penetrating element; it therefore has a lower surface disposed substantially perpendicular to a central axis of the skin penetrating element from which it extends.

As to newly submitted Claims 21 and 22, Reed et al. and Fye and Coates fail to disclose a skin penetrating element comprising barbs which are disposed at different distances from the base, and which define a half – pyramidal shape. However, Reed et al. disclose an element having barbs which are disposed at the same distance from the base (column 3, lines 60 – 66) and a barb width of 1 μm (column 3, lines 47 – 59). It would be obvious for one of ordinary skill in the art to vary the distances of the barbs from the base and the width of the barb (which will determine whether it has a half – pyramidal shape) since the distances of the barbs from the base and the width of the barb would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

ANSWERS TO APPLICANT'S ARGUMENTS

6. Applicant has made no arguments regarding the 35 U.S.C. 112, second paragraph rejection of Claims 1, 10 and 17, of record on page 2 of the previous Action; specifically, the term 'groove' and the phrase 'being configured' have not been defined; the rejection is therefore repeated.

Applicant's arguments regarding the 35 U.S.C. 103(a) of Claims 1 – 18 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No.

Art Unit: 1772

5,031,609) and Coates (U.S. Patent No. 4,219,019) have been considered but have not been found to be convincing for the reasons set forth below.

Applicant argues, on page 5 of paper No. 5, that amended Claim 19 overcomes the rejection because the only method of making the penetrating elements which Reed et al disclose is sequential etching of different layers of material. However, Reed et al teach that it is equivalent to use the same material or different materials for all of the layers (the base, support and head are made from plastic, or the base and support are made from Si and the head from SiO₂; column 3, lines 35 – 46); the claimed aspect of the backing and skin penetrating elements, including each barb, being made from the same plastic resin therefore reads on Reed et al.

Applicant also argues, on page 6, that Reed et al. do not disclose elements which are made by molding; the method of making used by Reed et al., Applicant argues, is photochemical etching. However, as stated on page 2 of the previous Action, the scope of the claims falls within the limitations of Reed et al. The method making the skin – penetrating element (product – by – process) is given little patentable weight. Applicant would need to demonstrate, by verified showing, the unexpected advantages accruing from making the elements by molding, rather than etching, as claimed.


Applicant also argues, on page 6, that Reed et al. disclose barbs which extend from the upper penetrating end (tip) of the element; amended Claims 1 and 19, Applicant argues, are directed to barbs which are spaced below the penetrating end. However, Reed et al disclose a penetrating element having a central portion with a pointed shape (three pointed edges, or barbs; column 3, lines 60 – 66; Figure 6); Reed et al. therefore also disclose barbs extending from a point spaced below the upper penetrating end.

Art Unit: 1772

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Patterson, whose telephone number is (703) 305-3537. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by phone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (703) 308-2364. FAX communications should be sent to (703) 305-3599. FAXs received after 4 P.M. will not be processed until the following business day.

M.A.P.


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772 11/19/01